REMARKS

The only issue outstanding in the Office Action mailed August 13, 2007, is the rejection of claims 9-16 under 35 U.S.C. 103. Claims 1 and 3-6 have been indicated to be free of the prior art, as noted at page 3 of the Office Action. Reconsideration of the remaining rejection, in view of the following discussion and the two attached Declarations under 37 C.F.R. 1.132, is respectfully requested.

At the outset, it is noted that claim 1 has been amended to change the transitional language from "consisting of" to *comprising*, and moreover to indicate that the preparation of this claim is in tablet form. Claim 9 has been similarly amended to change the "consisting essentially of" language of the composition to *comprising*. It is submitted that, in view of the following discussion, these broadened claims remain patentable.

Rejection Under 35 U.S.C. 103

Claims 9-16 have been rejected under 35 U.S.C. 103 over Reynolds '332 taken with Lindenbaum (WO '691). Reconsideration of this rejection is respectfully requested.

Reynolds discloses a pharmaceutical composition comprising a carrier and the reaction product of tertiary phosphine with thyroxine and 3, 5, 3 prime-L-triiodothyronine. See the abstract and col. 1 of the patent. Patentees teach pharmaceutical compositions in which solid carriers include "lactose, magnesium stearate, starch, sucrose, mannitol, sorbitol, cellulose powder, dicalcium phosphate, talc, stearic acid, gelatin, agar pectin, acacia and the like. "Suitable liquid carriers" include glycols, polyglycols, peanut oil, olive oil, sesame oil, alcohols and water. The Office Action admits, at page 2 that Reynolds fails to teach selection of gelatin, at least, from among the other materials identified as carriers. However, it is argued that Lindenbaum suggests the use of comparable pharmaceutical preparations containing levothyroxine or triiodothyronine and gelatin. Applicants respectfully disagree with this analysis. Lindenbaum is directed to "wound treatment formulations," where "wound" refers to wounds of the skin. See, for example, page 6, second paragraph. Pharmaceutical compositions of this invention involve a "delivery polymer," see page 6, paragraph 3 and page 16, the second full paragraph bridging to pages 17. Such delivery polymers include a hydrogel such as HEMA

(hydroxyethyl-methacrylate) or NVP (N-vinylpyrrolidone), polyethylene glycol (PEG), gelatin, agarose, methylcellulose and related hydrophilic cellulose polymers or collagen. The delivery polymer is stated to exhibit the added benefit of slowing formation of a scab on the wound. Such formulations in accordance with the invention are solutions or gels, see page 17, the second paragraph, or "creams, elixirs, powders and the like." See the first full paragraph at page 17. It is evident, however, from the disclosure (e.g., example 1) that to the extent powders are encompassed by the invention, they do *not* include gelatin. Note example 1 where a powder is reconstituted as a gel *using* gelatin in order to apply topically. Gels, creams, etc. are known in the art as "semi-solids", not solid formulations.

It is thus respectfully submitted that one of ordinary skill in the art looking to produce dosage units suitable for *oral administration*, such as the tablets, capsules, lozenges, etc. of Reynolds, would *not* look to the topical formulation disclosures of Lindenbaum for any suggestion of the use of gelatin, and, moreover, that the references do not suggest formulations using gelatin as a binder in "solid" formulation.

Moreover, such a selection of gelatin is proven to be non-obvious in view of the unexpected results attributable thereto. These unexpected results are evidenced by the Declaration under 37 C.F.R. 1.132, filed in parent application 09/700,421, a copy of which is appended hereto, and the additional Declaration submitted herewith. In the first Declaration, comparison is made between a formulation containing gelatin, and one containing the polymer HPMC, (hydroxypropylmethylcellulose). It is noted that methylcellulose is disclosed as a delivery polymer at page 17 of Lindenbaum. The declaration shows that, unexpectedly, where gelatin is substituted for HPMC as a binder, active agent content over time is significantly greater for compositions formulated with gelatin then the active agent content maintained for those formulated with HPMC. One of ordinary skill in the art would not expect such a beneficial and significant stability effect, for gelatin as opposed to any other materials in one or the other of the cited references. In the second Declaration it is shown that a formulation according to the invention, which contains a small amount (2.50 mg) of gelatin as binder has a better stability than the same formulation containing 3.50 mg HPMC, which is the most frequently used binder. The improvement of stability further increases with the amount of gelatin in a dose-dependent way.

Accordingly, it is submitted that this provides further evidence of the non-obviousness of the claims, and withdrawal of the rejection is respectfully requested.

The Claims of the application are submitted to be in condition for allowance. However, if the Examiner has any questions or comments, she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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